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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,470	04/06/2001	Richard W. Layne	1759.17208-FOR	6760

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 02/25/2004

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,470

Applicant(s)

LAYNE ET AL.

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 5, 6, 10, and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Applicant's election of Species 2: Figures 2 and 7 and J of Figure 28 are acknowledged.

Response to Amendment

The amendments to title, specification, and drawings are acknowledged.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7-9, 11, 12, 14, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mastrorio et al. in US Patent No. 5,849,014.

Regarding claim 1, Mastrorio et al. disclose a method of directing the expansion of an expandable structure within a bone, via introducing an expandable structure (16) into the bone; introducing a substantially rigid surface (20) into the bone at a location adjacent the expandable structure; and expanding the expandable structure within the bone, as recited in columns 3-4 and seen in figures 1-4.

Regarding claim 7, Mastrorio et al. disclose that as applied to claim 1, as well as, an expandable structure (16) that directly contacts the substantially rigid surface (20) during the expansion step, seen in figures 1-4.

Regarding claim 8, Mastrorio et al. disclose that as applied to claim 1, as well as, a substantially rigid surface (16) that resists displacement during the expansion step, as recited in column 4, lines 40-67.

Regarding claim 9, Mastrorio et al. disclose that as applied to claim 1, as well as, a substantially rigid surface that is a platform (20).

Regarding claim 11, Mastrorio et al. disclose that as applied to claim 1, as well as, contracting the expandable structure (16) and removing the structure from the bone, and introducing a filler material into the cavity, as recited in column 4, column 5, lines 1-20, and seen in figures 1-4.

Regarding claim 12, Mastrorio et al. disclose that as applied to claim 11, as well as, filler material that is bone cement, as recited throughout the specification.

Regarding claim 14, Mastrorio et al. disclose that as applied to claim 1, as well as, a substantially rigid surface (20) that extends along substantially the

entire length of the expandable structure, as seen in figures 1-4, depending on which direction and orientation the length is considered.

Regarding claim 19, Mastrorio et al. disclose a device for directing the expansion of an expandable structure (16), having a member having a proximal and a distal end and a lumen extending therethrough and a platform (20) extending adjacent the distal end, as recited throughout the specification and figures, depending on which orientation and direction the distal end is considered.

3. Claims 1, 2, 7-9, 11, 14, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Marchosky in US Patent No. 6,582,446.

Regarding claim 1, Marchosky et al. disclose a method of directing the expansion of an expandable structure (108) within a bone, via introducing an expandable structure (108) into the bone; introducing a substantially rigid surface (110) into the bone at a location adjacent the expandable structure; and expanding the expandable structure within the bone, as recited in column 5, and seen throughout the figures.

Regarding claim 2, Marchosky et al. disclose that as applied to claim 1, as well as, an expandable structure (108) that creates a cavity within the bone, as recited in column 5, lines 20-45 and throughout the specification.

Regarding claim 7, Marchosky et al. disclose that as applied to claim 1, as well as, an expandable structure (108) that directly contacts the substantially rigid surface (110) during the expansion step, as recited in columns 4 and 5 and seen throughout the figures.

Regarding claim 8, Marchosky et al. disclose that as applied to claim 1, as well as, a substantially rigid surface (110) that resists displacement during the expansion step, as recited in columns 4 and 5.

Regarding claim 9, Marchosky et al. disclose that as applied to claim 1, as well as, a rigid surface (110) that is a platform.

Regarding claim 11, Marchosky et al. disclose that as applied to claim 1, as well as, contracting the expandable structure (108) and removing the structure from the bone, and introducing a filler material into the cavity, as recited in columns 6 and 7.

Regarding claim 14, Marchosky et al. disclose that as applied to claim 1, as well as, a substantially rigid surface (110) that extends along substantially the entire length of the expandable structure, as seen in the figures, depending on which orientation the length is considered.

Regarding claim 19, Marchosky et al. disclose a device for directing the expansion of an expandable structure (108), the device having a member having a proximal and a distal end and a lumen extending therethrough and a platform (110) extending adjacent the distal end, as recited throughout the specification and seen in the figures.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrorio et al. in US Patent No. 5,849,014.

Regarding claims 13 and 20, Mastrorio et al. disclose that as applied to claims 1 and 19. However, Mastrorio et al. do not explicitly recite a substantially rigid surface that is stainless steel. On the other hand, stainless steel is extremely well known in the medical art and it would be obvious to one with ordinary skill in the art to have the rigid surface be of stainless steel for the purpose of proper rigidity.

6. Claims 3, 4, 12, 13, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchosky in US Patent No. 6,582,446.

Regarding claim 3, Marchosky et al. disclose that as applied to claim 1. However, Marchosky does not explicitly recite an expandable structure that compress at least a portion of a cancellous bone within the bone. On the other hand, Marchosky, applicant is directed to column 1, lines 5-30, where cancellous bone is within the scope of the invention although not explicitly recited.

Regarding claim 4, Marchosky et al. disclose that as applied to claim 1. However, Marchosky does not explicitly recite an expandable structure that displaces at least a portion of a cortical bone within the bone. On the other hand, Marchosky, applicant is directed to column 1, lines 5-30, where cortical bone is within the scope of the invention although not explicitly recited.

Regarding claims 12 and 18, Marchosky et al. disclose that as applied to claim 11 and as modified to claim 16. However, Marchosky does not explicitly recite filler material comprises bone cement. On the other hand, Marchosky, applicant is directed to column 1, lines 5-30, and column 7, lines 1-30 where bone cement is within the scope of the invention/immobilizing substance, although not explicitly recited.

Regarding claims 13 and 20, Marchosky et al. disclose that as applied to claims 1 and 19. However, Marchosky does not explicitly recite a substantially rigid surface that is stainless steel. On the other hand, Marchosky, applicant is

directed to column 1, lines 5-30, and column 7, lines 1-30 where bone cement is within the scope of the invention/immobilizing substance, although not explicitly recited. On the other hand, stainless steel is extremely well known in the medical art and it would be obvious to one with ordinary skill in the art to have the rigid surface be of stainless steel for the purpose of proper rigidity.

Regarding claims 15 and 17, Marchosky et al. disclose a method of treating a weakened, fractured or diseased bone, via introducing an insertion device; positioning the insertion device such that a platform (110) extending from a distal end of the insertion device is positioned between an expandable device (108) and a portion of the bone region; and expanding the expandable device and creating a cavity within the bone, as recited throughout the specification and discussed above. However, Marchosky et al. do not explicitly recite introducing an insertion device through a cortical bone region and into a cancellous bone region of the bone, where that insertion device is positioned between an expandable device and a portion of the cancellous bone region or expandable structure is introduced into the cancellous bone region through a lumen in the insertion device. On the other hand, Marchosky, applicant is directed to column 1, lines 5-30, where cortical bone and cancellous bone are within the scope of the invention although not explicitly recited.

Regarding claim 16, Marchosky et al. as modified disclose that as applied to claim 15, as well as filling the cavity with a bone filler, as discussed above.

Conclusion

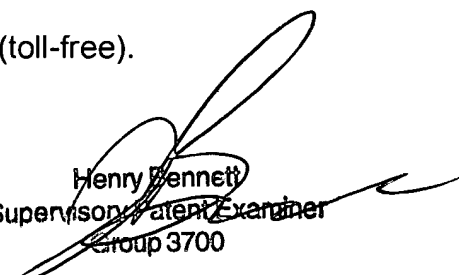
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2002/0099385; US 2002/0032447; US 2002/0010472; US Patent No. 5,792,044; and US Patent No. 5,788,703.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO


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